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TRANSMITTAL OF APPEAL BRIEF (Large Entity)

Docket No.
PB0169

In Re Application Of: **Yizhong Gu**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/060,830	January 20, 2002	Sheridan Swope	22840	1653	3442

Invention: **Human LCCL Domain Containing Protein**

COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on **February 14, 2005.**

The fee for filing this Appeal Brief is: **$500.00**

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Signature

Dated: **April 11, 2005**

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cc:

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Melissa Leck

Typed or Printed Name of Person Mailing Correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/060,830	Confirmation No.: 3442
Applicant	:	Yizhong Gu	
Filed	:	January 20, 2002	
TC/A.U.	:	1653	
Examiner	:	Sheridan Swope	
Docket No.	:	PB0169	
Customer No.	:	22840	

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

April 11, 2005

APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in triplicate, appealing from the November 12, 2004, rejection of the Primary Examiner, finally rejecting claims 1, 3-12, 32, 33 and 39 in the captioned application. The Notice of Appeal was filed on February 14, 2005, which contained authorization to charge the "Appeal Fee" to Appellants' Deposit Account.

Real Party in Interest

Amersham plc, owner of the captioned application, is the real party in interest to this appeal.

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Related Appeals and Interferences

There are no other appeals or interferences related to the instant appeal.

Status of Claims

Claims 1, 3-12, 32, 33 and 39 are pending in the captioned application and are currently under examination. Claims 2, 48 and 49 have been cancelled. Claims 13-31, 34-38 and 40-47 have been withdrawn from consideration. Claims 1, 3-12, 32, 33 and 39 are appealed and are reproduced in Appendix A, attached hereto.

Status of Amendments

There are no outstanding amendments with respect to the captioned application.

Summary of Invention

The invention provides isolated nucleic acids that encode LCP, including two isoforms, and fragments thereof, vectors for propagating and expressing LCP nucleic acids, host cells comprising the nucleic acids and vectors of the present invention. The invention further provides probes comprising the nucleic acids of the present invention, and microarrays comprising at least one such probe. The invention provides methods for producing a LCP polypeptide, including culturing a host cell transformed to contain the nucleic acid molecule which expresses the protein. The invention further provides pharmaceutical formulations of the nucleic acids of the present invention, and diagnostic compositions based on the LCP nucleic acids of the present invention.

Issues

1. Whether claims 1, 3-12, 32, 33 and 39 are properly rejected under 35 U.S.C. § 101 as lacking patentable utility.
2. Whether claims 1, 3-12, 32, 33 and 39 are unpatentable under 35 U.S.C. § 112, first paragraph, for lack of enablement.

Grouping of Claims

All of the rejected claims in the rejection appealed hereunder stand or fall together.

Arguments

1. Claims 1-12, 32, 33 and 39 are not properly rejected under 35 U.S.C. § 101 as lacking patentable utility.

The Examiner has rejected claims 1, 3-12, 32, 33 and 39 under 35 U.S.C. § 101 for lacking utility. In response, Appellants respectfully assert that the rejection is improper for the following reasons.

Appellants first note that the utility requirement of § 101 is met either if the claimed subject matter has a "well-established" utility, or if a substantial, specific, and credible utility is disclosed in the specification.

> An invention has a well-established utility (1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (*e.g.*, properties or applications of a product or process), and (2) the utility is specific, substantial, and credible.

Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001). For example, "some uses can be immediately inferred from a recital of certain properties." *In re Folkers*, 344 F.2d 970, 974 (C.C.P.A. 1965) (explicitly undisturbed by *Brenner* v. *Manson*, 383 U.S. 519, 535 n.23 (1966), and *In re Kirk*, 376 F.2d 936, 949 (C.C.P.A. 1967) (Rich, J., dissenting)). In particular, when "newly discovered compounds [that] belong to a class of compounds, the members of which have become well recognized as useful for a particular purpose because of a particular property, the only reasonable conclusion is that the new compounds, also possessing that property, are similarly useful." *Folkers* at 975, *see also* MPEP 2107.02.

Appellants respectfully submit that the claimed subject matter comprises nucleic acid sequences encoding a human LCP protein. The claimed LCP gene sequences encode trans-membrane polypeptides, with an N-terminal signal peptide (page 7, ll. 5 – 8). These polypeptides also contain an LCCL domain, mutations within which have been shown to cause the deafness disorder DFN9 in humans (page 6, ll. 19 – 23). Also included in the encoded polypeptides is a discoidin domain, with a predicted amphipathic, membrane binding alpha helical structure at the C-terminal (page 6, line 24 through page 7, line 4). The polypeptides encoded by the claimed gene sequences also contain a truncated CUB domain, an extracellular domain found in mostly developmentally regulated proteins (page 6, ll. 12 – 18). Appellants submit that the gene and encoded polypeptides of the instant invention are useful in developing therapeutics as well as diagnostics for neurological and developmental disorders and tumors.

Appellants further respectfully submit that post filing date literature by Koshikawa et al. also supports Appellants' utility assessment of the instant claimed

invention (see Koshikawa et al., *Oncogene*, 21:2822-2828, 2002; copy submitted during prosecution, and listed on Form PTO-1449, filed February 24, 2004). Koshikawa et al. presented evidence, supporting a specific and substantial use for the claimed invention. Koshikawa et al. showed that expression of the same gene as claimed is significantly up-regulated in a significant fraction of lung cancers *in vivo* with high frequency in metastatic lesions. This finding is in agreement with Appellants' statement that the gene and encoded polypeptides are useful in developing therapeutics as well as diagnostics for neurological and developmental disorders and tumors (page 5 line 30 through page 6, line 2; page 7, ll. 2 – 4).

Appellants further submit that it was well established, well before the instant application was filed, that one can use a gene sequence in disease diagnosis, prognosis and in the development of therapeutics and treatment. Also well know is the technique for prenatal diagnosis by mutation analysis of disease-causing genes. Further, the nucleotide sequences of these genes can be used as a reference to compare to gene sequences from patients or healthy individuals for mutation analysis, diagnosis and prognosis. Appellants submit that it is clear that the instantly claimed LCP gene is capable of similar uses.

In addition, Appellants submit that the nucleic acid sequences of the instantly claimed invention have multiple other utilities as well. Appellants submit that the nucleic acid sequences can be used as substrates on microarrays for expression analysis, including in cancer patients or patients with developmental disorders. Appellants submit that human whole genome microarrays containing every human gene are now offered by multiple vendors, including Affymetix (GeneChip^{TM}) and GE Healthcare (CodeLink^{TM}).

The usefulness of these arrays has been demonstrated by hundreds if not thousands of groups around the world, and proves the usefulness of the genes on these arrays.

Appellants submit that the sequences of the claimed nucleic acids can also be used as antisense inhibitors of the over-expressed genes in patients. The sequences can be used to produce proteins, antibodies or fusion proteins useful for the diagnosis and development of therapeutics as well. In addition, the nucleic acid sequences can be used to develop primers and probes, the primers can be used in PCR amplification of fragments of the gene, while the probes can be used for genomic as well as expression analysis. Appellants respectfully submit that the claimed invention is useful.

According to the Federal Circuit, "[t]he threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing **some identifiable benefit**." Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1366 (Fed. Cir. 1999) (emphasis added). Such, Appellants submit that Examiner's rejections cannot be sustained.

2. Claims 1-12, 32, 33, and 39 are not properly rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement

The Examiner also rejected claims 1, 3–12, 32, 33 and 39 under 35 U.S.C. § 112, first paragraph, for lack of enablement. According to the Examiner, since the claimed invention is not supported by either a convincing asserted utility or a well-established utility, one skilled in the art wound not know how to use the claimed invention.

Appellants respectfully submit that because the claimed inventions indeed display a patentable utility for the reasons advanced above, the derivative rejection for non-enablement would be in error if reasserted against these claims.

In view of the foregoing, Appellants respectfully assert that the Examiner's rejections cannot be sustained and should be reversed.

Conclusion

In view of the foregoing, Appellants respectfully assert that the Examiner's rejection cannot be sustained and respectfully requests the reversal of the rejection.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on April 11, 2005.

Signature: _____

Name: Melissa Leck

APPENDIX A

The Rejected Claims

Claim 1 (previously presented): An isolated nucleic acid, comprising:

(a) a nucleotide sequence selected from the group consisting of:

(i) the nucleotide sequence of SEQ ID NO: 1113 or SEQ ID NO: 1115;

(ii) a degenerate variant of the sequences set forth in (i);

(iii) a nucleotide sequence of SEQ ID NO: 1115; and

(iv) the complete complement of the sequences set forth in (i) – (iii); or

(b) a nucleotide sequence selected from the group consisting of:

(i) a nucleotide sequence that encodes a polypeptide having the sequence of SEQ ID NO: 1114 or SEQ ID NO: 1116;

(ii) a nucleotide sequence that encodes a polypeptide having the sequence of SEQ ID NO: 1116; and

(iii) a nucleotide sequence that is the complete complement of the nucleotide sequence of any one of (i) – (ii),

wherein said isolated nucleic acid encodes a protein involved in neurological and developmental disorders, as well as diseases involving cell-cell adhesion processes and wherein said isolated nucleic acid comprising a nucleotide sequence selected from group (b) is no more than about 100 kb in length.

Claim 2 (cancelled)

Claim 3 (original): The isolated nucleic acid of claim 1, wherein said nucleic acid, or the complement of said nucleic acid, is expressed in adrenal, adult liver, bone marrow, brain, fetal liver, heart, kidney, lung, placenta, skeletal muscle, colon and prostate, as well as a cell line, hela.

Claim 4 (previously presented): A nucleic acid probe, comprising:

(a) the nucleic acid of claim 1.

Claim 5 (original): The probe of claim 4, wherein said probe is detectably labeled.

Claim 6 (original): The probe of claim 4, attached to a substrate.

Claim 7 (original): A microarray, wherein at least one probe of said array is a probe according to claim 4.

Claim 8 (original): The isolated nucleic acid molecule of claim 1, wherein said nucleic acid molecule is operably linked to one or more expression control elements.

Claim 9 (original): A replicable vector comprising a nucleic acid molecule of claim 1.

Claim 10 (original): A replicable vector comprising an isolated nucleic acid molecule of claim 8.

Claim 11 (previously presented): A host cell transformed to contain the nucleic acid molecule of any one of claims 1 or 8 - 10, or the progeny of said host cell.

Claim 12 (original): A method for producing a polypeptide, the method comprising: culturing the host cell of claim 11 under conditions in which the protein encoded by said nucleic acid molecule is expressed.

Claim 13 (withdrawn): An isolated polypeptide produced by the method of claim 12.

Claim 14 (withdrawn): An isolated polypeptide, comprising:

(a) an amino acid sequence selected from the group consisting of SEQ ID NO: 3 and 1114;

(b) an amino acid sequence having at least 65% amino acid sequence identity to that of (a)(i) or (a)(ii);

(c) an amino acid sequence according to (a)(i) or (a)(ii) in which at least 95% of deviations from the sequence of (a)(i) or (a)(ii) are conservative substitutions; or

(d) a fragment of at least 8 contiguous amino acids of any of (a) – (c).

Claim 15 (withdrawn): A fusion protein, said fusion protein comprising a polypeptide of claim 14 fused to a heterologous amino acid sequence.

Claim 16 (withdrawn): The fusion protein of claim 15, wherein said heterologous amino acid sequence is a detectable moiety.

Claim 17 (withdrawn): The fusion protein of claim 16, wherein said detectable moiety is fluorescent.

Claim 18 (withdrawn): The fusion protein of claim 15, wherein said heterologous amino acid sequence is an Ig Fc region.

Claim 19 (withdrawn): An isolated antibody, or antigen-binding fragment or derivative thereof, the binding of which can be competitively inhibited by a polypeptide of claim 14.

Claim 20 (withdrawn): A transgenic non-human animal modified to contain the nucleic acid molecule of any one of claims 1 or 8 – 10.

Claim 21 (withdrawn): A transgenic non-human animal unable to express the endogenous orthologue of the nucleic acid molecule of claim 1.

Claim 22 (withdrawn): A method of identifying agents that modulate the expression of human LCP, the method comprising:

contacting a cell or tissue sample believed to express human LCP with a chemical or biological agent, and then

comparing the amount of human LCP expression in said cell or tissue sample with that of a control,

changes in the amount relative to control identifying an agent that modulates expression of human LCP.

Claim 23 (withdrawn): A method of identifying agonists and antagonists of human LCP, the method comprising:

contacting a cell or tissue sample believed to express human LCP with a chemical or biological agent, and then

comparing the activity of human LCP with that of a control,

increased activity relative to a control identifying an agonist, decreased activity relative to a control identifying an antagonist.

Claim 24 (withdrawn): A purified agonist of the polypeptide of claim 14.

Claim 25 (withdrawn): A purified antagonist of the polypeptide of claim 14.

Claim 26 (withdrawn): A method of identifying a specific binding partner for a polypeptide according to claim 14, the method comprising:

contacting said polypeptide to a potential binding partner; and

determining if the potential binding partner binds to said polypeptide.

Claim 27 (withdrawn): The method of claim 26, wherein said contacting is performed *in vivo*.

Claim 28 (withdrawn): A purified binding partner of the polypeptide of claim 14.

Claim 29 (withdrawn): A method for detecting a target nucleic acid in a sample, said target being a nucleic acid according to claim 1, the method comprising:

(a) hybridizing the sample with a probe comprising at least 17 contiguous nucleotides of a sequence complementary to said target nucleic acid in said sample under high stringency hybridization conditions, and

(b) detecting the presence or absence, and optionally the amount, of said binding.

Claim 30 (withdrawn): A method of diagnosing a disease caused by mutation in human LCP, comprising:

detecting said mutation in a sample of nucleic acids that derives from a subject suspected to have said disease.

Claim 31 (withdrawn): A method of diagnosing or monitoring a disease caused by altered expression of human LCP, comprising:

determining the level of expression of human LCP in a sample of nucleic acids or proteins that derives from a subject suspected to have said disease,

alterations from a normal level of expression providing diagnostic and/or monitoring information.

Claim 32 (original): A diagnostic composition comprising the nucleic acid of claim 1, said nucleic acid being detectably labeled.

Claim 33 (original): The diagnostic composition of claim 32, wherein said composition is further suitable for *in vivo* administration.

Claim 34 (withdrawn): A diagnostic composition comprising the polypeptide of claim 14, said polypeptide being detectably labeled.

Claim 35 (withdrawn): The diagnostic composition of claim 34, wherein said composition is further suitable for *in vivo* administration.

Claim 36 (withdrawn): A diagnostic composition comprising the antibody, or antigen-binding fragment or derivative thereof, of claim 19.

Claim 37 (withdrawn): The diagnostic composition of claim 36, wherein said antibody or antigen-binding fragment or derivative thereof is detectably labeled.

Claim 38 (withdrawn): The diagnostic composition of claim 37, wherein said composition is further suitable for *in vivo* administration.

Claim 39 (original): A pharmaceutical composition comprising the nucleic acid of claim 1 and a pharmaceutically acceptable excipient.

Claim 40 (withdrawn): A pharmaceutical composition comprising the polypeptide of claim 14 and a pharmaceutically acceptable excipient.

Claim 41 (withdrawn): A pharmaceutical composition comprising the antibody or antigen-binding fragment or derivative thereof of claim 19 and a pharmaceutically acceptable excipient.

Claim 42 (withdrawn): A pharmaceutical composition comprising the agonist of claim 24 and a pharmaceutically acceptable excipient.

Claim 43 (withdrawn): A pharmaceutical composition comprising the antagonist of claim 25 and a pharmaceutically acceptable excipient.

Claim 44 (withdrawn): A method for treating or preventing a disorder associated with decreased expression or activity of human LCP, the method comprising administering to a subject in need of such treatment an effective amount of the pharmaceutical composition of any of claims 39, 40 or 42.

Claim 45 (withdrawn): A method for treating or preventing a disorder associated with increased expression or activity of human LCP, the method comprising administering to a subject in need of such treatment an effective amount of the pharmaceutical composition of claim 41 or 43.

Claim 46 (withdrawn): A method of modulating the expression of a nucleic acid according to claim 1, the method comprising:

administering an effective amount of an agent which modulates the expression of a nucleic acid according to claim 1.

Claim 47 (withdrawn): A method of modulating at least one activity of a polypeptide according to claim 14, the method comprising:

administering an effective amount of an agent which modulates at least one activity of a polypeptide according to claim 14.

Claims 48-49 (cancelled)